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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

CTEP Support Contracts Forms and Surveys (National Cancer Institute)

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI) will publish periodic summaries of propose projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Michael Montello, Pharm. D., Cancer Therapy Evaluation Program (CTEP), 9609 Medical Center Drive, MSC 9742, Rockville, MD 20850 or call

non-toll-free number 240-276-6080 or E-mail your request, including your address to: montellom@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: CTEP Support Contracts Forms and Surveys, 0925-NEW National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Cancer Institute (NCI) Cancer Therapy Evaluation Program (CTEP) and the Division of Cancer Prevention (DCP) fund an extensive national program of cancer research, sponsoring clinical trials in cancer prevention, symptom management and treatment for qualified clinical investigators. As part of this effort, CTEP and DCP oversee two support programs, the NCI Central Institutional Review Board (CIRB) and the Cancer Trial Support Unit (CTSU). The

purpose of the support programs is to increase efficiency and minimizing burden. The NCI CIRB provides trial oversight satisfying the requirements of 45 CFR 45 and 21 CFR 56 for review of NCI supported studies. The CTSU provides program and systems support for regulatory document collection, membership, data management and patient enrollment. The two programs use integrated systems and processes for managing participant information and documentation of regulatory review.

To meet the responsibilities of each program, information is collected from the sites for purposes of membership, enrollment, opening of IRB approved studies, documenting IRB review, regulatory approval (for sites not using the CIRB), patient enrollment, and routing of case report forms.

Several surveys are collected to assess satisfaction and provide feedback to guide improvements with processes and technology. Other Surveys have been developed to assess health professional's interests in clinical trials.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 15,531.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CTSU IRB/Regulatory Approval Transmittal Form	Health Care Practitioner	2444	12	2/60	978
CTSU IRB Certification Form	Health Care Practitioner	2444	12	10/60	4,888
Withdrawal from Protocol Participation Form	Health Care Practitioner	279	1	10/60	47
Site Addition Form	Health Care Practitioner	80	12	10/60	160
CTSU Roster Update Form	Health Care Practitioner	600	1	5/60	50
CTSU Request for Clinical Brochure	Health Care Practitioner	360	1	10/60	60
CTSU Supply Request Form	Health Care Practitioner	90	12	10/60	180
Site Initiated Data Update Form	Health Care Practitioner	2	12	10/60	4
Data Clarification Form	Health Care Practitioner	150	24	10/60	600
RTOG 0834 CTSU Data Transmittal Form	Health Care Practitioner	12	76	10/60	152

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
MC0845(8233) CTSU Data Transmittal	Health Care Practitioner	5	12	10/60	10
CTSU Generic Data Transmittal Form	Health Care Practitioner	5	12	10/60	10
TAILORx_PACCT1_Data Transmittal Form	Health Care Practitioner	161	96	10/60	2576
Unsolicited Data Modification Form: Protocol: TAILORx/PACCT-1	Health Care Practitioner	30	12	10/60	60
CTSU Patient Enrollment Transmittal Form	Health Care Practitioner	12	12	10/60	24
CTSU Transfer Form	Health Care Practitioner	360	2	10/60	120
CTSU System Access Request Form	Health Care Practitioner	180	1	20/60	60
NCI CIRB AA & DOR between the NCI CIRB and Signatory Institution	Participants	50	1	15/60	13

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
NCI CIRB Signatory Enrollment Form	Participants	50	1	15/60	13
CIRB Board Member Biographical Sketch Form	Board Member	25	1	15/60	6
CIRB Board Member Contact Information Form	Board Member	25	1	10/60	4
CIRB Board Member W-9	Board Member	25	1	15/60	6
CIRB Board Member NDA	Board Member	25	1	10/60	4
CIRB Direct Deposit Form	Board Member	25	1	15/60	6
CIRB Member COI Screening Worksheet	Board Members	12	1	30/60	6
CIRB COI Screening for CIRB meetings	Board Members	72	1	15/60	18
CIRB IR Application	Health Care Practitioner	80	1	60/60	80
CIRB IR Application for Exempt Studies	Health Care Practitioner	4	1	30/60	2

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
CIRB Amendment Review Application	Health Care Practitioner	400	1	15/60	100
CIRB Ancillary Studies Application	Health Care Practitioner	1	1	60/60	1
CIRB Continuing Review Application	Health Care Practitioner	400	1	30/60	200
Adult IR of Cooperative Group Protocol	Board Members	65	1	180/60	195
Pediatric IR of Cooperative Group Protocol	Board Members	15	1	180/60	45
Adult Continuing Review of Cooperative Group Protocol	Board Members	275	1	60/60	275
Pediatric Continuing Review of Cooperative Group Protocol	Board Members	130	1	60/60	130
Adult Amendment of Cooperative Group Protocol	Board Members	40	1	120/60	80

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Pediatric Amendment of Cooperative Group Protocol	Board Members	25	1	120/60	50
Pharmacist's Review of a Cooperative Group Study	Board Members	10	1	120/60	20
CPC Pharmacist's Review of Cooperative Group Study	Board Members	20	1	120/60	40
Adult Expedited Amendment Review	Board Members	348	1	30/60	174
Pediatric Expedited Amendment Review	Board Members	140	1	30/60	70
Adult Expedited Continuing Review	Board Members	140	1	30/60	70
Pediatric Expedited Continuing Review	Board Members	36	1	30/60	18
Adult Cooperative Group Response to CIRB Review	Health Care Practitioner	30	1	60/60	30

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Pediatric Cooperative Group Response to CIRB Review	Health Care Practitioner	5	1	60/60	5
Adult Expedited Study Chair Response to Required Mod	Board Members	40	1	15/60	10
Pediatric Expedited Study Chair Response to Required Mod	Board Members	40	1	15/60	10
Reviewer Worksheet - Determination of UP or SCN	Board Members	360	1	10/60	61
Reviewer Worksheet - CIRB Statistical Reviewer Form	Board Members	100	1	60/60	100
CIRB Application for Translated Documents	Health Care Practitioner	100	1	30/60	50
Reviewer Worksheet of Translated Documents	Board Members	100	1	15/60	25

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Reviewer Worksheet of Recruitment Material	Board Members	20	1	15/60	5
Reviewer Worksheet Expedited Study Closure Review	Board Members	20	1	15/60	5
Reviewer Worksheet Expedited Review of Study Chair Response to CIRB-Required Modifications	Board Members	5	1	30/60	3
Reviewer Worksheet of Expedited IR	Board Members	5	1	30/60	3
Reviewer Worksheet - CPC - Determination of UP or SCN	Board Members	40	1	15/60	10
Annual Signatory Institution Worksheet About Local Context	Health Care Practitioner	400	1	40/60	267
Annual Principal Investigator Worksheet About Local Context	Health Care Practitioner	1800	1	20/60	600

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Study-Specific Worksheet About Local Context	Health Care Practitioner	4800	1	20/60	1600
Study Closure or Transfer of Study Review Responsibility Form	Health Care Practitioner	1680	1	15/60	420
UP or SCN Reporting Form	Health Care Practitioner	360	1	20/60	120
Change of SI PI Form	Health Care Practitioner	120	1	15/60	30
CTSU Website Customer Satisfaction Survey	Health Care Practitioner	275	1	15/60	69
CTSU Help Desk Customer Satisfaction Survey	Health Care Practitioner	325	1	15/60	81
CTSU OPEN Survey	Health Care Practitioner	60	1	15/60	15
CIRB Customer Satisfaction Survey	Participants	600	1	15/60	150
Follow-up Survey (Communication Audit)	Participants/ Board Members	300	1	15/60	75

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hours
Website Focus Groups, Communication Project	Participants/ Board Members	18	1	60/60	18
CIRB Board Member Annual Assessment Survey	Board Members	60	1	20/60	20
PIO Customer Satisfaction Survey	Health Care Practitioner	60	1	5/60	5
Concept Clinical Trial Survey	Health Care Practitioner	500	1	5/60	42
Prospective Clinical Trial Survey	Health Care Practitioner	1000	1	1/60	17
Low Accrual Clinical Trial Survey	Health Care Practitioner	1000	1	1/60	17
ETCTN PI Survey	Physician	75	1	15/60	19
ETCTN RS Survey	Health Care Practitioner	175	1	15/60	44
Totals		24,125	100,362		15,531

Dated: December 1, 2016

Karla Bailey

Project Clearance Liaison

National Cancer Institute, National Institutes of Health

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